Attachment E

U.S. DEPARTMENT OF AGRICULTURE FOOD SAFETY AND INSPECTION SERVICE INTERNATIONAL PROGRAMS REVIEW DATE

05/17/2000

NAME OF FOREIGN LABORATORY

FOREIGN COUNTRY I ARORATORY REVIEW

Kimron Veterinary Institute
National Residue Control Laboratory

ľ	CHEIGH	COUNTRY	LABORATORI	VEAICAA

FOREIGN GOV'T AGENCY
Veterinary Services & Animal Health
Ministry of Agri. & Rural Development

CITY & COUNTRY
Beit Dagan, ISRAEL

ADDRESS OF LABORATORY
P/O BOX 50250

NAME OF REVIEWER
Faizur R. Choudry, DVM

NAME OF FOREIGN OFFICIAL

Stefan Soback, DVM. ph.D, Head, National Residue Control Laboratory

- 41561					•		,					224001			
	Residue Code/Nan	ne 🕨	>	100	300	400	500	200	203	800	S/V				
so.	REVIEW ITEMS Sample Handling	01 02 ω 03	A	A	A	A	A	A	A	A					
	Sampling Frequency		A	A	A	A	A	A	A	A					
	Timely Analyses	03	02 03 04 04 05	A	A	A	A	A	A	٨	A				
	Compositing Procedure	04		o	o	o	0	0	0	0	0				
	Interpret Comp Data	05		0	0	0	O	0	0	0	0		!		
	Data Reporting	06		A	A	A	A	٨	A	٨	A				
ANALYTICAL PROCEDURES	Acceptable Method	07 w	A	A	A	A	A	A	A	A					
	Correct Tissue(s)	08	NO.	A	A	A .	A	A	A	A	A				
	Equipment Operation	,09	EVALUATION	С	С	С	С	С	С	A	A				
	Instrument Printouts	10	E	A	A	A	A	0	0	0	0				
QUALITY ASSURANCE PROCEDURES	Minimum Detection Levels	11		A	A	A	A	0	0	0	0				
	Recovery Frequency	12	٦	A	٨	A	A	0	0	0	0				
	Percent Recovery	13	000 2000 2000 2000 2000 2000 2000 2000		٨	A	A	0	0	0	0				
	Check Sample Frequency	14	EVALUATION	A	A	A	A	A	A	A	A				
Ĕ	All analyst w/Check Samples	15		С	c	С	C	С	C	С	С				
On'	Corrective Actions	16		С	A	A	A	A	A	A	A		<u> </u>		
	International Check Samples	17		A	A	A		A	A	A	A	i			
REVIEW PROCEDURES	Corrected Prior Deficiencies	18	EVAL, CODE	Å	c	c	; c		! C	i c	A	1	1	!	
OTHER REVIEW	:	19	EVAL. CODE			-	i	:	!		-	•			
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FOREIGN COUNTRY LABORATORY REVIEW			Y REVIEW	REVIEW DATE	NAME OF FOREIGN LABORATORY					
(Comment Sheet)			05/17/2000		Kimron Veterinary Institute National Residue Control Laboratory					
FOREIGN GOV'T AGENCY Veterinary Services & Animal Health Ministry of Agri. & Rural Development			CITY & COUNTRY Beit Dagan, ISR.	AEL	ADDRESS OF LABORATORY P/O BOX 50250					
NAME OF REVIEWER Faizur R. Choudry, DVM			NAME OF FOREIGN OFFICIAL Stefan Soback, DVM. ph.D, Head, National Residue Control Laboratory							
RESIDUE CODES	ITEM NO.		1	COMMENTS						
100,300, 400,500, 200,203, 800 100,300, 400,500, 200,203,	9	elements (TE), antible Laboratory Quality A. 1. Lot numbers, expurchased, were not 2. The record bool solutions were used b. 3. No record was a received. The check sample prohydrocarbons and or	rmation for chlorinated hydrocarbons (CHC), organophosphates (OP), hormones, trace ibiotics, chloramphenicol, and sulfonamides was not recorded in the official books for Assurance Program. expiration dates, and where the standard solutions/reagents/media ingredients were or recorded in the standards books. looks were not signed and verified by the supervisiors each time before the newly prepared d by the technicians or chemists. Is maintained for the corrective actions taken when unacceptable check sample results were program was not adequately maintained: no intralaboratory check samples for chlorinated organophosphates were carried out in March or April 2000, and no check samples at all were mones, trace elements, chloramphenicol, sulfonamides, or antibiotics as required.							
800	l to 17	Polychlorinated biph	nenyls (PCB's) wer	e not being analy	zed as required.					
300,400, 500,203, 800	18	chloramphenicol, an	d sulfonamides dur am will be implem	ing the last auditented immediatel	out for organophosphates, trace elements, hormones, GOI inspection officials indicated that intralaboratory but no corrections have been made except partially muary, February and May 2000.					

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United States
Department of
Agriculture

Food Safety And Inspection Service Technical Service Center Suite 300, Landmark Center 1299 Farnam Street Omaha. NE 68102

Questions for Auditing Laboratories

General

Name & location of lab:

Institute for Food Microbiology and Consumer Goods

Tirat Carmel 39100. ISRAEL.

5/15/2000

Private or gov't lab?

Private

How & when was accreditation obtained? By the Ministry of Health/ 5-17-1984

How & how often is accreditation maintained? Announced/sometime

unannounced visits and twice a year.

When and how is payment for analysis provided? *Monthly by the establishment*

Are results released before payment is received?

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What are the qualifications of the analyst(s) performing the individual tasks within a method? Total 7 analysts; 3 M.Sc & 3 B.Sc Microbiology and 1 Engineer.

What are the qualifications of the direct supervisor of the analyst(s)? *Dr. Irit Weiser, General Manager; Phd, in Food Microbiology,*

Methodology for HACCP Salmonella samples (regulatory labs)

Does this lab analyze HACCP Salmonella samples? yes

How are HACCP Salmonella samples received & recorded? Collected from each establishments by the laboratory personnal and recorded on laboratory log book.

Are HACCP Salmonella samples analyzed on the day of receipt? **Analyzed on the same day.**

What method(s) is used for HACCP Salmonella samples? USDA-FSIS-microbiology laboratory guide book. 3rd Edition-Chapter 4, 1998.

Is it a qualitative method (i.e. +/- result)?

yes.

Are HACCP ground beef samples analyzed for Salmonella? Yes (twoestablishments programmed one sample a month)

What is the size of the ground beef test portion?

1 kilos

What buffer (and what volume) is used for: and 225 ml buffer

Phosphate buffer: 25 grams meat

Sponge samples for Salmonella?

Poultry rinsates for Salmonella?

400ml

Salmonella ground beef sample homogenates? Yes with stomach machine

What is the formulation of the Buffered Peptone Water you use? Peptone 10.0g; sodium chloride 5.0g; disodium phosphate 3.5g; monopotassium phosphate 1.5g and distilled water 1 liter

What analytical controls are used for Salmonella analyses(i.e. control cultures, etc.)? Salmonella typharium 80 cc (14028)

Are they employed for each sample set?

ves

How are HACCP Salmonella results expressed?

(i.e. +/-results)

How are HACCP Salmonella results recorded:

Data sheets/work sheets? Data sheets

and/or Log books?

Log books

How and to whom are HACCP Salmonella results reported? In writing to GOI inspection officials

Are "check" samples periodically used to test the proficiency of the lab and analysts for Salmonella testing?

- 1. For individual analysts or for the lab as a whole? Individual analyst intralaboratory & Interlaboratory by the proficiency testing group in England (FEPAS)
- 2. What species/strains are used? Salmonella typhorium
- 3. How many samples are analyzed and how often? Three times a year (between 3-4 samples at a time)
- 4. Are both inoculated and uninoculated samples provided to analysts for the proficiency testing? **Inoculated**
- 5. How many colony-forming units (cfu) per gram are inoculated into the proficiency samples provided to analysts? 30 to 300 p/ml

Methodology for HACCP generic E. coli samples (in-plant or other private labs)

Does this lab analyze HACCP generic E. coli samples? Yes-biotype

How are HACCP E. coli samples received & recorded? Collected from the establishment and recorded on the log book.

Are HACCP E. coli samples analyzed on the day of receipt? Yes on the same day

What method is used for HACCP generic E. coli samples? USDA-FSIS Guideline E.coli.testing program Control Verification in poultry slaughter establishments July 1997 (3-tube MPN AOAC 17.2.02 & E.coli 17.2.02)

Is it a quantitative method?

yes

What buffer (and what volume) is used for:

Phosphate buffer 10 ml

E. coli sponge samples?

Poultry rinsates for generic E. coli?

Poultry rinsates

What analytical controls are used?

E.coli.

Are they employed for each sample set?

yes

How are HACCP E. coli results calculated and/or expressed? MPN Tube Index

How are E. coli results recorded:

Data sheets/work sheets? Data sheets & log books

Log books?

How and to whom are HACCP E. coli results reported? In writing to Veterinarian in charge

Are "check" samples periodically used to test the proficiency of the lab and analysts for generic E. coli testing? Intalaboratory check samples 3 times a year (between 3-4 samples at a time)

- 6. For individual analysts or for the lab as a whole? *Individual analysts*
- 7. What species/strains are used? E.coli strains 80 cc
- 8. How many samples are analyzed and how often? Intalaboratory check samples 3 times a year (between 3-4 samples at a time)
- 9. Are both inoculated and uninoculated samples provided to analysts for the proficiency testing? *Inoculated*
- 10. How many colony-forming units (cfu) per gram are inoculated into the proficiency samples provided to analysts? (10)2 & 910)4

NOTE: IF YOU HAVE ANY QUESTIONS REGARDING THIS, FEEL FREE TO CALL EITHER VICTOR COOK OR BONNIE ROSE AT 202-501-6022.